

REMARKS

This amendment is in response to the Office Action of June 3, 2010. Claims 1 and 22 have been amended. Claims 14-19 are withdrawn. Claims 24-27 have been cancelled. Claims 28-31 have been added. Claims 1-4, 6, 10-19, 22, 23, and 28-31 are currently pending. No new matter has been added.

§ 112 Rejections

Claims 1-4, 6, 10-13, and 22-27 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that, in regards to claims 1 and 27, there is no support in the originally-filed disclosure for a tubular outer covering or inner core that “extend[s] along the entire length of the body.” The Office Action asserts that, although Figures 4 and 5 each show a portion of the stylet having a tubular outer covering, nothing in the disclosure appears to indicate that this configuration extends along the entire length of the structure.

Although the Applicants disagree with these assertions, in the interest of moving forward with prosecution claim 1 has been amended to remove above-mentioned recitations and claim 27 has been cancelled. Accordingly, the Applicants respectfully request withdrawal of the rejections of claims 1-4, 6, 10-13, and 22-27.

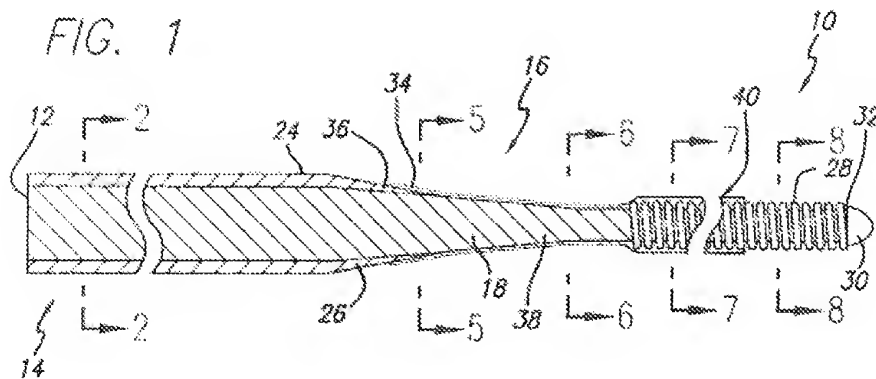
The Office Action further asserts that, in regard to claim 22, there is no support for a varying diameter of the inner core from one end to the other. Although the Applicants also disagree with this assertion, in the interest of moving forward with prosecution claim 22 has been amended to remove the phrase “from one end to the other.” Accordingly, the Applicants respectfully request withdrawal of the rejections of claims 1-4, 6, 10-13, and 22-27.

§ 102 and § 103 Rejections

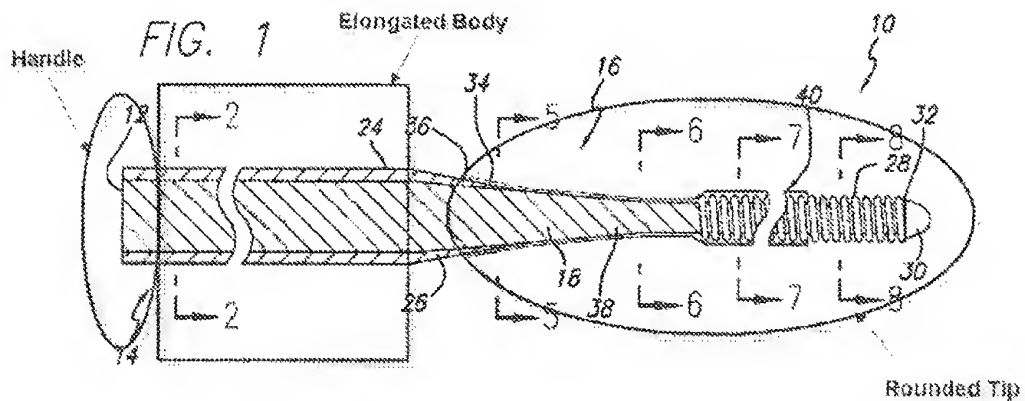
Claims 1, 10, 11, 23, and 25-27 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,165,140 to Ferrera (hereinafter "Ferrera"). Claims 1, 6, 10, 22, 23, and 25-27 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,069,226 to Yamauchi et al. (hereinafter "Yamauchi"). Claims 2-4, 12, and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of U.S. Patent 7,074,197 to Reynolds et al. (hereinafter "Reynolds"). Claims 6 and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera in view of Yamauchi. Claim 24 was rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrera (or Yamauchi) in view of U.S. Patent 5,357,961 to Fields et al. (hereinafter "Fields"). The Applicants traverse these rejections.

Claim 1 recites a stylet for use with a medical stimulating lead. The stylet includes an elongated body having a proximal end, a distal end, a length, and an isodiametric outer diameter along the length. The stylet also includes a handle disposed at the proximal end of the body. The handle has an outer diameter that is larger than the outer diameter of the body. The stylet further includes a rounded tip glued or welded directly to the distal end of the body such that a proximal end of the rounded tip is isodiametric with the distal end of the body.

Claim 1 was separately rejected as being anticipated by each of Ferrera and Yamauchi. Neither Ferrera nor Yamauchi teaches or suggests a stylet having a rounded tip glued or welded directly to the distal end of the body such that a proximal end of the rounded tip is isodiametric with the distal end of the body. Ferrera discloses a composite guidewire having an elongate core with a distal tapered portion and a reinforcement tube disposed over a proximal portion of the core (Ferrera, Abstract). Figure 1 of Ferrera is provided below.



As shown in Figure 2 of Ferrera, the composite guidewire 10 has an elongate core 12 with a distal tapered portion 18 and a reinforcement tube 24 disposed over a proximal portion 14 of the core 12 (Ferrera, col. 3 lines 1-18). A distal tip 30 is disposed at the distal end of the core 12 (Ferrera, col. 3 lines 33-35). The Office Action provides an alternate interpretation of the “tip” disclosed by Ferrera, as shown below.



As shown in the above drawing provided in the Office Action, the rounded tip is interpreted as including the tapered portion 18 of the core 12. Regardless of how the “tip” is interpreted, the tip does not have a proximal end that is isodiametric with the distal end of an isometric body, as recited in claim 1. Moreover, if one of skill in the art were to interpret the “tip” as including the tapered

portion 18 of the core 12, then the “tip” fails to meet the recitation of being glued or welded directly to the distal end of the body, as also recited in claim 1, because the tapered portion 18 is not glued or welded to the remainder of the core 12.

Moreover, forming a tip such that a proximal end of the tip is isodiametric with the distal end of an isodiametric body amounts to more than a mere design choice. Providing a tip with a proximal end that is isodiametric with the distal end of an isodiametric body may improve the ability of a user to maneuver the stylet within a patient, as compared to a stylet having a tip coupled to a tapered region at the distal end of a stylet body. For example, providing a tip with a proximal end that is isodiametric with the distal end of an isometric body may provide consistent movement (*e.g.*, sliding, twisting, rotating, bending, or the like) along the entire length of the stylet. In contrast, a stylet body having a tip coupled to a tapered region at the distal end of a stylet body may provide different bending properties along the tapered distal end of the stylet. For example, the tapered distal region may have a different stiffness than an untapered region. Additionally, the tapered distal end may encounter a different amount of resistance than untapered region(s) with the walls of the lumen within which the stylet is disposed. These variable stiffnesses and resistances may cause the stylet to move differently along those portions of the stylet than the untapered region of the stylet. These different movements may be difficult to account for when maneuvering the stylet while disposed in the patient and may, therefore, potentially cause harm to the patient. Accordingly, in some cases any advantages received by altering the bending properties of a distal region of the stylet may be outweighed by an increased amount of uncertainty to a user of the stylet with regards to how the distal region will respond during insertion of the stylet into the patient.

Yamauchi discloses a catheter guidewire for use in guiding a catheter to a destination position in blood vessels (Yamauchi, Abstract). The catheter guidewire includes a solid core wire formed from Nitinol and an outer jacket covering the core wire (Yamauchi, Abstract). Figure 1 of Yamauchi is provided below.

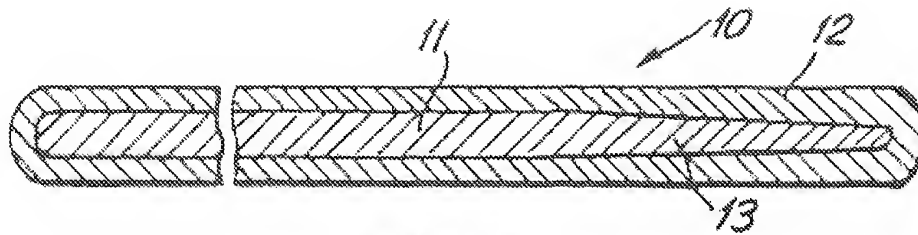


FIG. 1

As shown in Figure 1 of Yamauchi, the catheter guidewire 10 includes a solid core wire 11 and an outer jacket 12 covering the core wire 11 (Yamauchi, col. 3 lines 8-12). Yamauchi discloses that the opposite ends of the jacket 12 are formed round and are configured and arranged to be plastically deformed into a desired shape (Yamauchi, col. 2 lines 5-9; and col. 3 lines 23-24). There is no teaching or suggestion in Yamauchi of coupling a rounded tip to a distal end of the catheter guidewire 10. Thus, Yamauchi does not teach or suggest a rounded tip glued or welded directly to the distal end of the body such that a proximal end of the rounded tip is isodiametric with the distal end of the body, as recited in claim 1.

Accordingly, neither Ferrera nor Yamauchi, alone or in combination, teach or suggest all of the elements of claim 1. The additional cited references fail to cure the deficiencies of Ferrera and Yamauchi. For at least these reasons claim 1, as well as claims 2-4, 6, 10-19, 22, 23, and 28-31 which depend therefrom, are patentable over the cited references. The Applicants respectfully request withdrawal of the rejections of these claims.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue. If the Examiner has any questions or concerns, the Applicant(s) encourage(s) the Examiner to contact the Applicants' representative, Patrick Turner, by telephone to discuss the matter.

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Respectfully submitted,

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